



COVID-19 Outbreak Control and Prevention State Cell

Health & Family Welfare Department

Government of Kerala

ADVISORY FOR PERFORMING RAPID ANTIGEN DIAGNOSTIC ASSAY FOR COVID-19

NO: 31/F2/2020/H&FWD- 2nd July 2020

The ICMR has recommended rapid antigen assay kit for diagnosis of COVID-19. This is a point of care rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. The test has moderate sensitivity but very high specificity. This can be used to rule in the disease. The assay approved by ICMR is known as "Standard Q COVID-19 Ag kit"

1.KEY NOTE REGRADING RAPID ANTIGEN DIAGNOSTIC ASSAY

1. Nasopharyngeal secretion is the biological sample to be taken for antigen-based testing. ONLY a nasopharyngeal swab should be taken for rapid antigen-based test using **standard Q Ag-kit**
2. Each test kit comes with an in built COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
3. The swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs. The usual VTM or Modified VTM should not be used for sample collection
4. Once the sample goes into the extraction buffer, it should be mixed properly and the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are to be put into the well of the test strip.
5. The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. Maximum duration for interpreting a positive or negative test is 30 minutes.



6. The results should be interpreted by a Senior Lab Technician/ Microbiologist/ Medical Doctor.
7. The DSO shall constitute or utilise the sample collection teams already formed based on previous advisories issued related to testing. WISK (Walk in Sample Kiosks)/ Mobile Medical Collection units could be used for sample collection.
8. A testing facility (Clean space/ Clean Room) may be set up in places where samples are collected. The samples collected should be collected and tested within one hour and time should not be wasted in sending the samples to the laboratory far away.
9. The test strip should be discarded after interpreting according to the Biomedical waste management rules.
10. The test kit should be stored between 2° to 30° C.

2. SETTINGS FOR APPLICATION OF RAPID ANTIGEN ASSAY TESTS

1. Airport for testing expatriates
2. Sentinel Surveillance
3. Testing in Cluster Containment Zones

2.1 AIRPORT

All symptomatic people arriving at airport need to be isolated to COVID hospital / CFLTC and to be offered RTPCR.

All other people eligible as per the GO (Rt) No 31/ F2/2020/ Health- 25th June 2020 need to be tested. Antigen-based test may be used for testing expatriates.

Sample Requisition Form (SRF) for the same is attached as annexure 1 & 2. Annexure 1 alone can be used if real time request through ICMR portal can happen.



2.2 SENTINEL SURVEILLANCE

Antigen based tests could be used for sentinel surveillance. Groups for sentinel surveillance as per advisory issued on sentinel surveillance on 14th May are as follows:

Gr -1	Patients in general population with Acute Respiratory Infection (ARI)	-
Gr- 2	Health Care Workers in Non-COVID settings	a. Hospitals (Doctors, Nurses, Paramedics etc) b. General Practitioners c. Ambulance Drivers d. Others
Gr- 3	Persons with high social exposure	a. Food delivery persons b. Community Volunteers (ASHA, LSG volunteer) c. Provisions shop vendors d. Ration Shop e. wholesale fruits or vegetable vendors f. Police Personnel g. Media Personnel h. Health Staff at Field (JHI, JPHN etc)
Gr- 4	Natives of Kerala who came in close contact with Truck Drivers arriving from outside state	a. Head load workers b. Vendors in market places c. Street vendors d. Warehouse- in- charges e. People at Vehicle Transit Camps (no travel history) f. FSW & MSM
Gr- 5	Guest workers	-
Gr- 6	Epidemiological Samples	-
Gr- 7	Samples from Expatriates/ People with Travel history outside state in last 14 days.	b) Person with travel history from red zone districts (outside Kerala) c) Persons with travel history outside Kerala not belonging to above two sub-categories

***Gr-7a** has been removed from this form.

Sample Requisition form for the same is attached as annexure- 1 & 3. Annexure 1 alone can be used if real time request through ICMR portal can happen.



2.3 TESTING IN CLUSTER CONTAINMENT ZONE

Antigen based tests could be used for augmented testing in cluster containment zones.

Rapid Antigen Test for COVID-19. (Standard Q COVID- Ag Kit)	
Cluster Category	Description
Cluster category-1 (Health Care Workers in cluster containment zone)	Health Care Workers in the cluster containment zone: 1a. Hospitals (Doctors, Nurses, Paramedics etc) in the cluster containment area 1b. General Practitioners in local clinics 1c. Health Staff at Field (JHI, JPHN etc) 1d. ASHA, Anganwadi worker 1e. Ambulance Drivers 1f. Others.
Cluster Category-2 (Persons with high Social Exposure in the cluster containment zone)	Persons with high Social Exposure in the cluster containment zone: 2a. LSG Members 2b. LSG Volunteers 2c. Food delivery persons 2d. Ration shop/Provisions/fruits/vegetable shop vendors/shop owners 2e. Police Personnel 2f. Media Personnel 2g. Auto/Taxi/Bus drivers 2h. Persons in fuel pumps/stations 2i. Workers employed in cleaning public places 2.J. Bank and other office staff 2.k. others
Cluster Category-3 (General population- to be sampled)	3.General Population: a. Pregnant women b. Post natal women c. Elderly (>60 yrs) d. Children less than 10yrs e. Persons with co-morbidities f. Others
Cluster Category-4 (Guest workers in the cluster containment zone)	4.Guest workers
Cluster Category-5 (Epidemiological samples- Neighbours around the confirmed	5. Epidemiological samples: People in the neighbourhood of confirmed cases but not having any history any contact with the confirmed case or travel history.



case but without exposure to the case or travel history)	
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a. Sampling method for Cluster Category-3: General Population

Wards/Divisions to be randomly selected. Various simple random sampling methods like calculator method, lottery method, simple random generator applications etc may be used for this purpose. The DSO shall execute this process. Medical officers in charge and supervisors of respective institutions shall provide the updated information to the DSO.

Once the wards are selected a sufficiently large map of each ward should be selected and placed on a table. A pen or pencil should be placed on the map and rotated. The closest road/street on which the fine point of the pen or pencil stops rotating should be selected for the survey. **Five** such **roads/streets** should be randomly selected using the method described earlier before starting the survey. The sampling collection can start from either end of the road/street (both sides) to **select 5 houses**. Once 5 houses are selected and sampled the sample collection team can move to the other selected roads/streets. **A maximum of two members in the house** can be sampled according to the priority mentioned below:

- a. Pregnant women
- b. Post natal women
- c. Elderly (>60 yrs)
- d. Children less than 10yrs
- e. Persons with co-morbidities
- f. Others

b. Cluster Category-4: Guest workers

A sample of the guest workers in each panchayath and municipality should be tested.

The DSO shall list all the guest worker camps in **LSG divisions**. Medical officers in charge and supervisors of respective institutions shall provide the updated information to the DSO.

From the list of camps in each LSGs, camps should be randomly selected from the list using simple random sampling methods described earlier.



The sample collection team shall visit the camps and make a list of all the workers present at the time and choose **5** workers using simple random methods and collect the biological samples and test.

- c. **CLUSTER CATEGORY-5:** Epidemiological samples- People in the **neighbourhood of confirmed cases(no history)** but not having any history of contact with the confirmed case or travel history outside the state/country in the last 14 days are eligible to be selected. **50 houses around the residence of confirmed cases without history should be selected for the purpose.** All the individuals in the household may be selected. The DSO may take additional samples or modify the area of collection based on the epidemiological situation of the area.
- d. The Medical Officer in charge of the area shall identify the testing facilities/laboratories/institutions and persons in charge for this purpose in the cluster containment zone so as to provide the test as a point of care test.
- e. SRF for the same is attached as Annexure 1 & 4. Annexure 1 alone can be used if real time request through ICMR portal can happen.

3.INTERPRETATION OF TEST RESULTS

All positive samples are to be treated as confirmed cases and managed as per the existing guidelines. No need to reconfirm the positive results with any tests.

If the sample is negative in a symptomatic person, RT-PCR should be performed on a fresh sample from the patient. All COVID suspects to complete their quarantine period even if the test result is negative.

Further Information: ICMR guidelines regarding antigen tests can be obtained through the following link.
https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf. Video available at
<https://www.youtube.com/watch?v=mBdaOHJWxl4&feature=youtu.be>



4. RECORDING AND REPORTING

The DSO shall register with **ICMR** to obtain the login credentials for data entry through the email ID: ag-govthosp@icmr.gov.in. All test results (both positive and negative) are also to be entered in ICMR portal with the login ID and password issued by ICMR for the purpose.

The DSO should also register in the **Kerala government online portal (Healthmon)** for real time reporting. All results should be entered in the following link: <https://healthmon.kerala.gov.in/rapidtest> real time.

Daily Summary (12 noon-12 noon of previous day) of total tests should be entered at 12 noon every day at <https://healthmon.kerala.gov.in/rapidtest> under daily summary


Principal Secretary



Annexure-1

Annexure 1

NEW RPT

**Specimen Referral Form (SRF) ID information for
COVID-19 (SARS-CoV), in RT-PCR app- Kerala**

SRF ID

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Patient Name _____

Phone number

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Lab Name _____

**Sample Type (ICMR Category

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Routine sample	<input type="checkbox"/>	(refer category list)	SS Category	<table border="1"><tr><td>SS</td><td></td><td></td></tr></table>	SS			RTPCR	<input type="checkbox"/>
SS									
Sentinel surveillance	<input type="checkbox"/>				XPRT	<input type="checkbox"/>			
Airport surveillance	<input type="checkbox"/>				TRUENAT	<input type="checkbox"/>			
Cluster containment	<input type="checkbox"/>	CC Category	<table border="1"><tr><td>CC</td><td></td><td></td></tr></table>	CC			ANTIGEN	<input type="checkbox"/>	
CC									

(Please tick relevant boxes)

Sample to be pooled

Yes	No
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*Priority sample

Yes	No
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† Postmortem sample/ prisoners/ patients awaiting emergency intervention



Category Of Samples For Ready Reference At Collection Centre & Laboratories.

Category	ICMR Routine samples
1	Symptomatic international traveler in last 14 days
2	Symptomatic contact of lab confirmed case
3	Symptomatic health care worker/ frontline worker
4	Hospitalised SARI patient
5a	Asymptomatic direct high risk contact of lab confirmed case(family member)
5b	Asymptomatic health care worker in contact with confirmed case without adequate protection
6	Influenza like illness(ILI) in hospital
7	Pregnant woman in/near labor
8	Symptomatic (ILI) among returnees & migrants(within 7 days of illness)
9	Symptomatic ILI patient in Hotspot/ Containment
Others	-Please specify; select only if patient does not belong to category 1-8 OR -sentinel surveillance samples

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Group	Sentinel Surveillance samples
SS 1	Patients in general population with Acute Respiratory Infection (ARI)
SS 2a	Doctors, Nurses, Paramedics etc in Non-COVID settings
SS 2b	General Practitioners etc in Non-COVID settings
SS 2c	Ambulance Drivers in Non-COVID settings
SS 2d	Other health care staff in Non-COVID settings
SS 3a	Food delivery person
SS 3b	Community Volunteers (ASHA, LSG volunteer)
SS 3c	Provisions shop vendors
SS 3d	Ration Shop staff
SS 3e	wholesale fruits or vegetable vendors
SS 3f	Police Personnel
SS 3g	Media Personnel
SS 3h	Health Staff at Field (JHI, JPHN etc)
SS 4a	Head load workers who come in contact with Truck Drivers
SS 4b	Vendors in market places who come in contact with Truck Drivers
SS 4c	Street vendors who come in contact with Truck Drivers
SS 4d	Warehouse- in- charges who come in contact with Truck Drivers
SS 4e	People at Vehicle Transit Camps (no travel history)
SS 4f	FSW& MSM who come in contact with Truck Drivers
SS 5	Guest workers
SS 6	Epidemiological Samples
SS 7a	Passengers travelled in aeroplane/ship cabin/train/ road in last 14 days to Kerala
SS 7b	Person with travel history from red zone districts (outside Kerala) in last 14 days
SS 7c	Persons with travel history outside Kerala not belonging to above two sub-categories



CLUSTER CATEGORY	CLUSTER CONTAINMENT CATEGORIES
CC 1a	Hospitals (Doctors, Nurses, Paramedics etc) in the cluster containment area
CC 1b	General Practitioners in local clinics
CC 1c	Health Staff in the Field (JHI, JPHN etc)
CC 1d	ASHA, Anganwadi worker
CC 1e	Ambulance Drivers
CC 1f	Others.
CC 2a	LSG Members
CC 2b	LSG Volunteers
CC 2c	Food delivery persons
CC 2d	Ration shop/Provisions/fruits/vegetable shop vendors/shop owners
CC 2e	Police Personnel
CC 2f	Media Personnel
CC 2g	Auto/Taxi/Bus drivers
CC 2h	Persons in fuel pumps/stations
CC 2i	Workers employed in cleaning public places
CC 2j	Bank and other office staff
CC 2k	others
CC 3a	Pregnant women
CC 3b	Postnatal women
CC 3c	Elderly (>60 yrs)
CC 3d	Children less than 10yrs
CC 3e	Persons with co-morbidities
CC 3f	Others
CC 4	Guest workers in the cluster containment zone
CC 5	Epidemiological samples in cluster containment zone

**Annexure 2****Government of Kerala****COVID-19 TESTING AT AIRPORT USING RAPID ANTIGEN ASSAY**

SAMPLE ID NO: _____ / _____ / _____ (DISTRICT / DATE / SAMPLE NO.)

Name:			
Age:		Gender: Male/ Female/ Other	
Address			
District		Phone Number:	
Name of LSG			

COVID JAGRATHA ID:

1. Is the subject Symptomatic? YES / NO

2. If Symptomatic; data of onset of first symptoms: ____/____/____

Standard Q Test Result:	Positive	Negative	Inconclusive
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Annexure 3: Government of Kerala
COVID-19 SENTINEL SURVEILLANCE ACTIVITY USING RAPID ANTIGEN ASSAY

SAMPLE ID NO: _____ / _____ / _____ (DISTRICT /DATE/SAMPLE NO.)

Name:		
Age:		Gender: Male/ Female/ Other
Address		
District		Phone Number:
Name of LSG		

1. Is the subject Symptomatic? YES / NO

2. If Symptomatic; data of onset of first symptoms: ____/____/____

3. Which Out of the SEVEN groups the sample belongs to? (Please **CIRCLE** the relevant box and sub section)

Gr - 1	Patients in general population with Acute Respiratory Infection (ARI)	-
Gr - 2	Health Care Workers in Non-COVID settings	e. Hospitals (Doctors, Nurses, Paramedics etc) f. General Practitioners g. Ambulance Drivers h. Others
Gr - 3	Persons with high social exposure	i. Food delivery persons j. Community Volunteers (ASHA, LSG volunteer) k. Provisions shop vendors l. Ration Shop m. wholesale fruits or vegetable vendors n. Police Personnel o. Media Personnel p. Health Staff at Field (JHI, JPHN etc)
Gr - 4	Natives of Kerala who came in close contact with Truck Drivers arriving from outside state	a. Head load workers b. Vendors in market places c. Street vendors d. Warehouse- in- charges e. People at Vehicle Transit Camps (no travel history) f. FSW & MSM
Gr - 5	Guest workers	-
Gr - 6	Epidemiological Samples	-



Gr- 7	Samples from Expatriates/ People with Travel history outside state in last 14 days.	b) Person with travel history from red zone districts (outside Kerala) c) Persons with travel history outside Kerala not belonging to above two sub-categories		
		Standard Q Test Result:	Positive	Negative



Annexure 4

Government of Kerala

RAPID ANTIGEN ASSAY IN CLUSTER CONTAINMENT ZONES

SAMPLE ID NO: _____/SQ/ _____ / _____ (LSG name /SQ/DATE/SAMPLE NO.)

[eg. Ponnani/SQ/ 03-07-2020/ 004]

Name		LSG
Age:		Gender: Male/ Female/ Other
Phone Number		
District		
Address		
Occupation		

Symptoms:	Yes /N o	Date of onset;/...../.....	Previously diagnosed with COVID-19	Yes/No
Travel outside Kerala /country in last 14 days	Yes /N o	If yes.....	Physiological status	Pregnant / postnatal / lactating
Travelled outside the containment zone in the last 14 days:	Yes /N o	If yes.....	Comorbidity	Yes/No
Contact with any COVID suspect:	Yes /N o			

Rapid Antigen Assay COVID-19. (Standard Q COVID- Ag Kit)

Cluster group	Description
Cluster group-1 (Health Care Workers in cluster containment zone)	Health Care Workers in the cluster containment zone: 1a. Hospitals (Doctors, Nurses, Paramedics etc) in the cluster containment area 1b. General Practitioners in local clinics 1c. Health Staff in the Field (JHI, JPHN etc) 1d. ASHA, Anganwadi worker 1e. Ambulance Drivers. 1f. Others.
Cluster group-2 (Persons with high Social Exposure in the cluster containment zone)	Persons with high Social Exposure in the cluster containment zone: 2a. LSG Members 2b. LSG Volunteers 2.c Food delivery persons 2d. Ration shop/Provisions/fruits/vegetable shop vendors/shop owners 2e. Police Personnel 2f. Media Personnel 2g. Auto/Taxi/Bus drivers 2h. Persons in fuel pumps/stations 2.i. Workers employed in cleaning public places 2.j. Bank and other office staff 2.k. others
Cluster group-3	3.General Population 3.a. Pregnant women 3.b Postnatal women 3.c Elderly (>60 yrs)



	3.d. Children less than 10yrs 3.e. Persons with co-morbidities 3.f. Others
Cluster group-4 (Guest workers in the cluster containment zone)	4.Guest workers in the cluster containment zone
Cluster group-5 (Epidemiological samples)	5.Epidemiological samples in cluster containment zone

Standard Q Test Result:	Positive	Negative	Inconclusive
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